potentially detrimental to the study. The CCF COMS project has received U.S. Public Health Service support from 1985 to the present through subcontract funds from a National Eye Institute cooperative agreement award to the COMS Coordinating Center, The Wilmer Ophthalmological Institute, The Johns Hopkins Medical Institutions, Baltimore, Maryland. Because the COMS is an ongoing study, no publications were affected by the falsfified or fabricated data, and no clinical treatment has been based on the results of the study.

FOR FURTHER INFORMATION CONTACT: Director, Division of Research Investigations, Office of Research Integrity, 301–443–5330.

Lyle W. Bivens,

Director, Office of Research Integrity.

[FR Doc. 95–4765 Filed 2–24–5; 8:45 am]

BILLING CODE 4160–17–P

Centers for Disease Control and Prevention

[Announcement Number 524]

Injury Control Research Program Project Grants

Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1995 funds for Injury Control Research Program Project Grants (RPPGs). The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of ''Healthy People 2000,'' a PHS-led national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority areas of Violent and Abusive Behavior and Unintentional Injuries. For ordering a copy of ''Healthy People 2000,'' see the Section Where to Obtain Additional Information.

Authority

This program is authorized under Sections 301 and 391–394 of the Public Health Service Act (42 U.S.C. 241 and 280b-280b-3). Program regulations are set forth in 42 CFR part 52.

Smoke-Free Workplace

PHS strongly encourages all grant recipients to provide a smoke-free workplace and to promote the nonuse of all tobacco products, and Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, and early childhood development services are provided to children.

Eligible Applicants

Eligible applicants include all nonprofit and for-profit organizations. Thus, universities, colleges, research institutions, hospitals, other public and private organizations, State and local health departments, and small, minority and/or women-owned businesses are eligible for these grants. Applicants from non-academic institutions should provide evidence of a collaborative relationship with an academic institution. Special consideration may be given to applicants that emphasize the training of women and minorities. Current recipients of CDC injury control research program project grants are eligible to apply.

Availability of Funds

Approximately $1,000,000 is available in FY 1995 to fund one new and two recompeting RPPG awards. At least one of these three awards will be for a successfully competing RPPG focusing on youth violence. New and recompeting awards will be made for a 12-month budget period within a project period of up to three years. The amount of funding available may vary and is subject to change. Beginning award dates for each submission are shown in the ''Receipt and Review Schedule'' section of this announcement. Continuation awards within the project period will be made on the basis of satisfactory progress and the availability of funds.

RPPG awards will not exceed $400,000 per year (total direct and indirect costs) with a project period not to exceed three years. Subject to program needs and the availability of funds, supplemental awards to expand/enhance existing projects may be made. Supplemental awards may range from up to $100,000 to up to $200,000 per year (total direct and indirect costs). The range of supplemental funds is dependent upon the degree of comprehensiveness of the RPPG in addressing: research and training or research, training, and demonstration as determined by the Injury Research Grants Review Committee (IRGRC).

Incremental levels for supplemental awards (subject to program needs and the availability of funds) for successfully competing or recompeting RPPGs will be determined as follows:

RPPG addresses research and training—Up to $100,000

RPPG addresses research, training, and demonstration—Up to $200,000

Purpose

The purposes of this program are:

A. To support injury prevention and control research on priority issues as delineated in: ''Healthy People 2000,'' ''Injury Control in the 1990's: A National Plan for Action,'' ''Injury in America,'' ''Injury Prevention: Meeting the Challenge,'' and ''Cost of Injury: A Report to the Congress.'' Information on these reports may be obtained from the individuals listed in the section.

Where to Obtain Additional Information

B. To support RPPGs as part of CDC's national extramural investment in injury control research and training, intervention development, and evaluation;

C. To integrate collectively, in the context of a national program, the disciplines of engineering, epidemiology, medicine, biostatistics, public health, law and criminal justice, and behavioral and social sciences in order to prevent and control injuries more effectively;

D. To identify and evaluate current and new interventions for the prevention and control of injuries;

E. To bring the knowledge and expertise of RPPGs to bear on the development and improvement of effective public- and private-sector programs for injury prevention and control; and

F. To facilitate injury control efforts supported by various governmental agencies within a geographic region.

Program Requirements

Essential Requirements for RPPGs:

A. Applicants must demonstrate and apply expertise (defined as: conducting ongoing high quality injury research and publication in peer reviewed scientific and technical journals(s) in the phases (prevention, acute care, or rehabilitation) or disciplines (e.g., biomechanics and epidemiology) of injury control which the research program addresses.

B. Applicants must document ongoing injury-related research projects or control activities currently supported by other sources of funding.

C. Applicants must provide a director (Principal Investigator) who has specific authority and responsibility to carry out the project. The director should report to an appropriate institutional official (e.g., dean of a school, vice president of a university, or commissioner of health). The director must have no less than 30% effort devoted solely to this project with an anticipated range of 30% to 50%.

D. Applicants must demonstrate experience in: conducting, evaluating, and publishing injury control research; developing, conducting, and evaluating injury control training curricula (researcher and/or practitioner) ; and/or designing, implementing, and evaluating injury control demonstration programs.

E. Applicants must provide evidence of working relationships with outside agencies and other entities which will allow for implementation of any proposed intervention activities.

F. Applicants must provide evidence of involvement of specialists or experts in medicine, engineering, epidemiology, law and criminal justice, behavioral and social sciences, biostatistics, and/or public health as needed to complete the plans of the RPPG. These are considered the disciplines and fields for RPPGs.

G. Applicants must specify mechanisms for linking the injury control research findings with public health (i.e. State and local organizations) and other intervention efforts to facilitate rapid translation, dissemination, and application of research findings preferably within three years of inception.

H. Applicants should clearly describe and be able to demonstrate how several proposed multiple research projects interrelate and complement each other. Outcome objectives of the research should be stated such that accomplishments clearly reflect elements of each individual project within the RPPG.

I. Applicants must have the ability to disseminate injury control research findings, translate them into interventions, and evaluate their effectiveness.

J. Applicants involved in training activities must be able to accomplish A-I above and have an established curricula and graduate training programs (researcher and/or practitioner) in disciplines relevant to injury control (e.g., epidemiology, biomechanics, safety engineering, traffic safety, behavioral sciences, or economics).

K. Applicants involved in training and demonstration activities must be able to accomplish A-J above and conduct demonstration projects (including description of statistical/ epidemiologic methodology and data sources to be used) aimed at determining the effectiveness of interventions, in terms of impact and cost, as part of a national injury prevention and control effort.

For the youth violence RPPG, in addition to research, training, and demonstration activities described in the Essential Requirements for RPPGs, of particular interest are projects designed to: a) develop further understanding of the relationship between social and economic influences (e.g., poverty, joblessness, concentration of poverty) and violent behavior, b) evaluate policies, programs, or interventions for reducing the impact of social and economic factors on violent behavior among youth and c) provide training for youth violence prevention researchers and practitioners.

Grant funds will not be made available to support the provision of direct care. Studies may be supported which evaluate methods of care and rehabilitation for potential reductions in injury effects and costs. Studies can be supported which identify the effect on injury outcomes and cost of systems for pre-hospital, hospital, and rehabilitative care and independent living.

Eligible applicants may enter into contracts, including consortia agreements (as set forth in the PHS Grants Policy Statement, dated October 1, 1990, as amended), as necessary to meet the requirements of the program and strengthen the overall application.

Evaluation Criteria

Upon receipt, applications will be reviewed by CDC staff for completeness and responsiveness as outlined under the previous heading Program Requirements, (A listing of where these requirements are described and/or documented in the application will facilitate the review process.). Incomplete applications and applications that are not responsive will be returned to the applicant without further consideration.

Applications which are complete and responsive may be subjected to a preliminary evaluation by reviewers from the Injury Research Grants Review Committee (IRGRC) to determine if the application is of sufficient technical and scientific merit to warrant further review. CDC will withdraw from further consideration applications judged to be noncompetitive and promptly notify the principal investigator/program director and the official signing for the applicant organization.

Those applications judged to be competitive will be further evaluated by a dual review process. The primary review will be a peer evaluation (IRGRC) of the scientific and technical merit of the application. The final review will be conducted by the CDC Advisory Committee for Injury Prevention and Control (ACIPC), which will consider the results of the peer review together with program need and relevance. Funding decisions will be made by the Director, National Center for Injury Prevention and Control (NCIPC), based on merit and priority score ranking by the IRGRC, program review by the ACIPC, and the availability of funds.

A. Review by the Injury Research Grants Review Committee (IRGRC)

Peer review of RPPG grant applications will be conducted by the IRGRC, which may recommend the application for further consideration or not for further consideration. Site visits will be a part of this process for recompeting RPPGs. Site visits may be a part of this process for new applicants.

Factors to be considered by IRGRC include:

1. The specific aims of the application, e.g., the long-term objectives and intended accomplishments.

2. The scientific and technical merit of the overall application, including the significance and originality (e.g., new topic, new method, new approach in a new population, or advancing understanding of the problem) of the proposed research.

3. The extent to which the evaluation plan will allow for the measurement of progress toward the achievement of stated objectives.

4. Qualifications, adequacy, and appropriateness of personnel to accomplish the proposed activities.

5. The soundness of the proposed budget in terms of adequacy of resources and their allocation.

6. The appropriateness (e.g., responsiveness, quality, and quantity) of consultation, technical assistance, and training in identifying, implementing, and/or evaluating intervention/control measures that will be provided to public and private agencies and institutions, with emphasis on state and local health departments, as evidenced by letters detailing the nature and extent of this commitment and collaboration. Specific letters of support or understanding from appropriate governmental bodies must be provided.

7. Evidence of other public and private financial support.

8. Progress thus far made as detailed in the application if the applicant is submitting a competitive renewal application. Documented success examples include: development of pilot projects; completion of high quality research projects; publication of findings in peer reviewed scientific and technical journals; number of professionals trained; integration of disciplines; translation of research into implementation; impact on injury

control outcomes including legislation/regulation, treatment, or behavior modification interventions.

B. Review by CDC Advisory Committee for Injury Prevention and Control (ACIPC)

Factors to be considered by ACIPC include:

1. The results of the peer review.
2. The significance of the proposed activities as they relate to national program priorities and the achievement of national objectives.
3. National and programmatic needs and geographic balance.
4. Overall distribution of the thematic focus of competing applications; the nationally comprehensive balance of the program in addressing: the three phases of injury control (prevention, acute care, and rehabilitation); the control of injury among populations who are at increased risk, including minority groups, the elderly and children; the major causes of intentional and unintentional injury; and the major disciplines of injury control (e.g., biomechanics and epidemiology).
5. Within budgetary considerations the ACIPC will establish annual funding levels as detailed under the heading, Availability of Funds.

C. Applications for Supplemental Funding

Supplemental grant awards may be made when funds are available, to support research work or activities. Applications should be clearly labeled to denote their status as requesting supplemental funding support. These applications will be reviewed by the IRGRC and the ACIPC.

D. Continued Funding

Continuation awards within the project period will be made on the basis of the availability of funds and the following criteria:

1. The accomplishments of the current budget period show that the applicant's objectives as prescribed in the yearly workplans are being met;
2. The objectives for the new budget period are realistic, specific, and measurable;
3. The methods described will clearly lead to achievement of these objectives;
4. The evaluation plan allows management to monitor whether the methods are effective by having clearly defined process, impact, and outcome objectives, and the applicant demonstrates progress in implementing the evaluation plan; and
5. The budget request is clearly explained, adequately justified, reasonable, and consistent with the intended use of grant funds.

Award Priorities

Special consideration will be given to recompeting Injury Control Research Program Projects Grants.

E.O. 12372 Review

Applications are not subject to the review requirements of Executive Order 12372, entitled Intergovernmental Review of Federal Programs.

Public Health System Reporting Requirement

This program is not subject to the Public Health System Reporting Requirement.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance Number is 93.136.

Other Requirements

A. Human Subjects

If the proposed project involves research on human subjects, the applicant must comply with the Department of Health and Human Services Regulations, 45 CFR part 46, regarding the protection of human subjects. Assurance must be provided to demonstrate that the project will be subject to initial and continuing review by an appropriate institutional review committee. The applicant will be responsible for providing assurance in accordance with the appropriate guidelines and form provided in the application kit.

B. Animal Subjects

If the proposed project involves research on animal subjects, the applicant must comply with the ''PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions.'' An applicant organization proposing to use vertebrate animals in PHS-supported activities must file an Animal Welfare Assurance with the Office for Protection from Research Risks at the National Institutes of Health.

Application Submission and Deadlines

A. Preapplication Letter of Intent

In order to schedule and conduct site visits as part of the formal review process, potential applicants are encouraged to submit a nonbinding letter of intent to apply to the Grants Management Officer (whose address is given in this section Item B). It should be postmarked no later than one month prior to the submission deadline (April 1, 1995, for May 1, 1995, submission deadline). The letter should identify the relevant announcement number for the response, indicate the submission deadline which will be met, name the principal investigator, and specify the injury control theme or emphasis of the proposed RPPG (e.g., acute care, biomechanics, epidemiology, prevention, or rehabilitation). The letter of intent does not influence review or funding decisions, but it will enable CDC to plan the review more efficiently.

B. Applications

Applicants should use Form PHS–398 (Rev. 9/91, OMB Number 0925–0001) and adhere to the ERRATA Instruction Sheet for PHS–398 contained in the Grant Application Kit. The narrative section for each project within an RPPG should not exceed 25 typewritten pages. Refer to section 4, page 10, of PHS–98 instructions for font type and size. Applications not adhering to these specifications may be returned to applicant. Applicants should submit an original and five copies to Henry S. Cassell, III, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E–13, Atlanta, GA 30305, in accordance with the submission date shown in the ''Receipt and Review Schedule'' listed below.

C. Deadlines

Applications shall be considered as meeting the deadline above if they are either:

1. Received on or before the deadline date; or

2. Sent on or before the deadline date and received in time for submission to the peer review committee. Applicants should request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.

Applications which do not meet the criteria in C.1. or C.2. above are considered late applications and will be returned to the applicant. Supplemental materials received later than thirty days after the application receipt date are considered late and will be returned to the applicant.

D. Receipt and Review Schedule

This is a continuous announcement. Consequently, these receipt dates will be ongoing until further notice. The proposed timetables for receiving applications and awarding grants are as follows:

Receipt of new/revised/ supplementary/ competitive renewal applications	Initial review	Secondary review	Earliest award date
May 1, 1995 ...	June ..	July ...	Aug. 1, 1995.

FUTURE RECEIPT DATES ARE AS FOLLOWS:

Receipt of new/revised/ supplementary/ competitive renewal applications	Initial review	Secondary review	Earliest award date
April	June ..	July ...	Aug.

Where to Obtain Additional Information

All application procedures and guidelines are contained within this program announcement. Business management technical assistance may be obtained from Maggie Slay, Grants Management Specialist, Centers for Disease Control and Prevention (CDC), 255 East Paces, Ferry Road, NE., Mailstop E13, Atlanta, GA 30305, telephone (404) 842–6797. Programmatic technical assistance may be obtained from Tom Voglesonger, Program Manager, Injury Control Research Centers, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, Mailstop K58, Atlanta, GA 30341–3724, telephone (404) 488–4265.

Potential applicants may obtain a copy of ''Healthy People 2000'' (Full Report, Stock No. 017–001–00474–0) or ''Healthy People 2000'' (Summary Report; Stock No. 017–001–00473–1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 783–3238.

Dated: February 21, 1995.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 95–4684 Filed 2–24–95; 8:45 am]

BILLING CODE 4163–18–P

Food and Drug Administration

[Docket No. 94D–0386]

Revised FDA Form 3210 Application for Establishment License for Manufacture of Biological Products (4/94); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the revised FDA Form 3210 Application for Establishment License for Manufacture of Biological Products (4/94). This form replaces the previous edition of FDA Form 3210 (12/88). FDA Form 3210 is used by manufacturers to apply for licensure of a facility for the manufacture of biological products regulated under the Public Health Service Act. The form has been revised because of inadequacies in the previous form that resulted in requests by the agency for supplemental information. The revised form is intended to shorten review time and decrease expenditure of resources for both the agency and industry.

DATES: FDA will continue to accept submissions using the previous Form 3210 (12/88) until August 28, 1995.

FOR FURTHER INFORMATION CONTACT: Timothy W. Beth, Center for Biologics Evaluation and Research (HFM–635), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–3074.

ADDRESSES: Submit written requests for single copies of the revised FDA Form 3210 Application for Establishment License for Manufacture of Biological Products (4/94) to Division of Congressional and Public Affairs (HFM–11), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–1800. Requests should be identified with the docket number found in brackets in the heading of this document. Send two self-addressed adhesive labels to assist that office in processing your requests. The form may also be obtained by calling the CBER FAX Information System at 301–594–1939 from a FAX machine with a touch tone phone attached or built in. FDA Form 3210 Application for Establishment License for Manufacture of Biological Products (4/94) is available for public examination in the Dockets Managements Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

SUPPLEMENTARY INFORMATION: FDA is making available revised FDA Form 3210 Application for Establishment License for Manufacture of Biological Products (4/94). The form was revised due to inadequacies in the old form which made the application review process cumbersome and difficult for both the agency and industry. In the past, the review process was often significantly lengthened because of requests by the agency for supplemental information from the manufacturer in order to ensure the safety, purity, potency, and efficacy of manufactured biological products. The revised form details more specifically the information that is required for establishment licensure. FDA believes that the revised form will expedite the review process by reducing the need for supplemental information requests and responses.

The revised form solicits information from the manufacturer in the following areas: (1) General information (names and addresses); (2) water systems; (3) heating ventilation and air conditioning systems; (4) raw materials and ancillary facilities; (5) source materials; (6) propagation of host systems; (7) intermediate processing; (8) formulation and final product preparation; (9) computer systems; (10) support areas; (11) quality control areas; (12) animal facilities for testing; (13) animal facilities for production; (14) calibration and validation; and (15) records.

In addition, the revised form also requires the following information to be submitted: A description of the lot numbering system, an organizational chart, an environmental assessment report, written agreements, curriculum vitae for key manufacturing and responsible personnel, and an overview of the current good manufacturing practices (CGMP) training program. A comments section is provided on the revised form for additional information that the manufacturer deems to be appropriate but may not be covered under other sections.

Manufacturers preparing to submit applications for establishment licensure should now utilize the revised (4/94) form. FDA will continue to accept submissions using the previous (12/88) form until August 28, 1995. Because the old form does not address specific questions and issues that are present on the revised form, additional review cycles should be anticipated when using the previous form.

Under the Paperwork Reduction Act of 1980 (Pub. L. 96–511) all forms requesting a collection of information